

REMARKS

Claims 1-32 are pending in the application.

Claims 24-27 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite. The claims have been amended to depend from claim 23 to obviate the rejection.

Claims 1-3, 5, 6, 10-12, 16 and 17 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 6,030,162 to Huebner. The applicant respectfully traverses the rejection for the following reasons.

First, claim 1 has been amended to state that each of the sections of the fixation pin is solid. This is in distinction to the hollow, tubular tension screw of Huebner. Even with respect to Fig. 20 of Huebner which has an apparently closed distal end, the teaching suggests that the screw is otherwise hollow: "screw 710 is similar to screw 10 [which is clearly hollow as shown in Fig. 3], but having an unthreaded leading extension 742 and an unthreaded trailing extension 744." (col. 8, lines 51-53).

Second, claim 1 has been amended to include additional limitations, including the limitation of now canceled claim 13; i.e., that the second portion of the pin is provided with a plurality of longitudinal grooves extending crosswise through at least one of said second threads, said grooves being located adjacent said shaft portion and spaced-apart

about an outer circumference of said second portion. None of the prior art teaches or suggests grooves about an outer circumference that extend crosswise through threads of the "second portion" and are located adjacent the shaft portion.

Third, claim 16 is not anticipated by Huebner, as Huebner fails to teach "a driver member including a *socket* having structure adapted to interfere with said negative spaces" on the outer circumference of the pin. Moreover, such a driver member is not suggested by Huebner as Huebner clearly teaches that a driver extends *internally* within the screw. There is no member with a *socket* (i.e., a hole or recess shaped to receive an object) which fits over and about an end of the screw in Huebner.

Fourth, claim 16 requires that "said second portion adjacent said shaft portion [defines] a plurality of longitudinal spaced apart negative spaces." This is not shown or suggested by Huebner.

Fifth, claim 17 claims "a mill tool having structure adapted to remove bone and define an opening in the bone *into which said socket* of said driver member can be inserted." This is not shown or suggested by Huebner.

For the foregoing reasons, claims 1-3, 5, 6, 10-12, 16 and 17 are allowable over Huebner.

Claims 1, 2, 4, 6, 10-14, 16, 18, 19, 21-23, 25, and 27-32 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Pub. No. 2003/0074002 A1 to West, Jr. ('West'). The applicant respectfully traverses the rejection for the following reasons.

First, with respect to independent claims 1, 16, 18, 21, 23 and 31, the examiner has failed to address the issue of the longitudinal grooves or negative spaces. In addition, each of such claims has been amended to clarify that the longitudinal grooves or negative spaces are spaced apart about "an *outer* circumference". West fails to teach such longitudinal grooves. If the examiner is interpreting the drive socket 24 of West as defining the grooves, there is no teaching or suggestion West that (1) the second portion is solid, (2) that the grooves extend crosswise through at least one of said second threads, (3) that the grooves are located adjacent the shaft portion, and (4) that the grooves are spaced-apart about an *outer* circumference of the threaded second portion. One or more of these limitations are required by all of the claims.

Second, claims 16, 21 and 31 all require a system including a driver having a "socket" with structure that interferes with the grooves. West fails to teach or suggest a *driver with a socket*, as the driving is performed with a shaft that extends *within a drive socket in the screw*, and not about an outer end of the screw. (¶¶ 53 and 54). That is, West teaches an inverse relationship of elements, and the claimed relationship is not suggested by West as an external driver would be incompatible with the slanted face 14 at the proximal end of the West screw.

Further, many of the dependent claims have limitations which are not taught or suggested by West. For example, claim 4 requires a conical tip of a defined angle which is not present or suggested by the West screw, and claims 22 and 32 require a mill tool for creating a hole in bone *"into which said socket of said driver member can be inserted."* This is not shown or suggested by West.

For the foregoing reasons, claims 1, 16, 18, 21 and 31 and all claims dependent thereon are allowable over West.

Claims 7-9 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Huebner in view of U.S. Pat. No. 6,193,719 to Gourney et al. The applicant respectfully traverses the Examiner's rejection for the following reasons.

First, for the reasons provided with respect to claim 1 from which these claims depend, the claims are allowable over the cited art.

Second, the references fail to suggest the claimed invention because there is no proper incentive to provide the frangible head of Gournay to the screw of Huebner for the following reasons.

The devices are not analogous art. Under the test set forth in In re Wood, 202 USPQ 171 (CCPA 1979), art is analogous if it is (1) from the same field of endeavor or if it is (2) reasonably pertinent to the particular problem with which the inventor is

involved. This test was interpreted by the Federal Circuit in In re Clay, 23 USPQ2d 1058 (Fed. Cir. 1992), where the Federal Circuit noted that even where two references were related to the use of gel in improving the flow of petroleum fluids, they were not from the same field of endeavor and the reference was not reasonably pertinent to the particular problem with which Clay was involved. In the present case, the bone screw of Huebner and the clamping plug of Gournay which clamps two implants together are clearly not in the same field of endeavor. In addition, the Gournay plug is not reasonably pertinent to the problem of the invention. The problem of the invention is when providing a fixation pin having a non-threaded shaft portion which is frangibly connected to a threaded portion of the pin, how to withdraw the screw *after* the pin has been inserted *until the threaded portion is flush with or slightly recessed into the bone and the non-threaded shaft portion is removed from the pin*. See Spec. at page 4, line 15 through page 5, line 22; page 11, line 14, page 12, line 8.

In addition, the Gournay plug includes machine threads which are specifically intended for interconnecting two implants or anchorage elements ("The threaded part may be screwed in a tapped hole provided in the corresponding implant, or on the screw thread of the body of a vertebral anchorage element . . .", col. 1, lines 37-39), while the Huebner screw includes self-tapping threads intended for insertion into bone.

Therefore, the Gournay clamping plug is not from the same field of endeavor and does not seek to solve the same problem as the invention. Thus, Gournay is not analogous art.

Moreover, even if the references were analogous art, there would be no appropriate suggestion to pull elements of one and combine such with elements of the other, absent a reconstruction based upon applicant's disclosure. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." In re Keller, 202 U.S.P.Q. 500 (C.C.P.A. 1979). Further, "[i]t is impermissible to first ascertain factually what the [inventor] did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct [inventor's] invention from such prior art." Panduit Corp. v. Dennison Mfg. Co., 227 U.S.P.Q. 337, 343 (Fed. Cir. 1985)(citing In re Shuman, 361 F.2d 1008, 1012, 150 U.S.P.Q. 54, 57 (C.C.P.A. 1966).

Third, in the claimed fixation pin and in the Huebner screw, it is not desirable to have *any* breakage due to excessive torque. In such devices that are insertable directly into bone, the devices generally must seat at a desired depth, regardless of the torque. However, in the machine screw of Gournay, the clamping force to join two implant elements (as indicated by the torque force) is what is desired to be controlled. There is no suggestion to apply a teaching with respect to torque forces to implants intended to directly seat within the bone at a desired depth. Specifically, it is noted that the shaft portion of the claimed screw is intended to remain connected to the fixation pin until the

pin is full seated, and only then is it frangibly disengaged by bending or cutting, not by torque:

The pin 10 is inserted until the intersection of the second portion 16 and the shaft portion 26 lies flush with, or more preferably slightly recessed relative to, the surface of the distal fragment. The shaft of the pin is then removed from the pin, e.g., by bending or cutting. (Spec. at page 10, line 25 – page 11, line 4)

For the foregoing reasons, claims 7-9 are allowable over the cited art.

Claims 13 (the limitation of which has been included in amended claim 1), 15 and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Huebner in view of U.S. Pat. No. 6,454,772 to Jackson. The applicant respectfully traverses the examiner's rejection for the following reasons.

First, as with Huebner and Gournay, Huebner and Jackson are screws with different purposes: Huebner is specifically designed for insertion directly into bone, and Jackson is specifically a set screw intended to be inserted in pre-formed threads in an implant device. Therefore, the devices are not analogous, and it would not be obvious to pull elements of one and combine such with elements of the other, absent a reconstruction based upon applicant's disclosure. The above discussion with respect to Huebner in view of Gournay regarding the case law of non-analogous art, obviousness and hindsight is applicable here.

Second, with respect to claims 1 and 15, such claims require that the shaft portion is solid. Huebner and Jackson each teach substantially hollow devices.

Third, with respect to claims 1, 15 and 18, the claims require that the "grooves extend crosswise through at least one of said second threads." In Jackson, the grooves do not extend crosswise through any threads. Rather, the drive slots 46 are located in a tubular hex head portion of the screw. Further, there is no suggestion in Jackson to provide such slots to the threaded portion of the screw. The hex shape and drive slots of the head of the screw are both provided for driving the screw (see col. 8, lines 11-20). After the head is sheared off by application of torque forces, there are no outer circumferential slots or grooves to facilitate removal of the remaining set screw.

Therefore, claims 1, 15 and 18 are allowable over the cited art.

Claims 13 (the limitation of which is now included in claim 1), 15, 18, 20, 23, 24 and 26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over West in view of Jackson. The applicant respectfully traverses the examiner's rejection for the following reasons.

First, as with 'Huebner in view of Gournay' and 'Huebner in view of Jackson', West and Jackson are screws with different purposes: West is specifically designed for insertion directly into bone, and Jackson is specifically a set screw with machine threads intended to be inserted in pre-formed threads in an implant device. Therefore, the devices are not analogous, and it would not be obvious to pull elements of one and combine such with elements of the other, absent a reconstruction based upon applicant's



disclosure. The above discussion with respect to Huebner in view of Gournay regarding the case law of non-analogous art, obviousness and hindsight is applicable here.

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Fourth, claim 23, as amended requires a plurality of *longitudinal grooves on the threaded portion* which extend *parallel to a longitudinal axis* of said pin and which are *located adjacent said shaft portion* and *spaced-apart about an outer circumference* of said threaded portion. West already teaches internal grooves into which a driver can be positioned to rotatably drive the screw into and out of a hole. As such, there is no need for, and thus no incentive to provide to West the proximal drive slots 46 of Jackson. Clearly, such a combination could only be made hindsight. Thus, the above discussion

with respect to Huebner in view of Gournay regarding the case law of non-analogous art, obviousness and hindsight is applicable here.

Further, as discussed above, it is not clear from the references how such slots would even be provided to West in view of the slanted face 14 at the proximal end of the West screw. How could grooves be provided about the "circumference"? Moreover, even if such a combination were proper, the combination fails to teach or suggest grooves on a threaded portion but located adjacent a shaft portion.

Fifth, claim 24 requires that the grooves interrupt the threads. This is certainly not taught or suggested by the combination. As stated above, West is already provided with a means for removal.

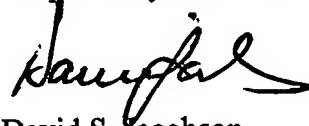
Sixth, claim 26 requires that each of the grooves has a depth which extends below the threads at a location of the grooves. The combination of West in view of Jackson, while inappropriate, nevertheless still fails to teach or suggest grooves at the location of the threads which extend below the threads.

For the foregoing reasons, claims 1, 15, 18, 20, 23, 24 and 26 are allowable over the cited art.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain

outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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